REMARKS

I. Amendments

By this amendment, new claims 20-29 have been added and claims 14-17 have been cancelled.

This amendment adds no new matter to the specification. Support for this amendment is found in the specification and claims as filed.

No amendment of inventorship is necessitated by this amendment.

II. Discussion of the Withdrawal of Claims 14-17

The Examiner has indicated that claims 14-17 have been withdrawn, as directed to a non-elected invention. Accordingly, Applicants have cancelled these claims.

III. Discussion of the Rejection under 35 U.S.C. Sec. 103(a)

The rejection of claims 1-7 and 13-19 for obviousness over the Ohno *et al.*, U.S. Patent No. 5,958,453 in view of Shashoua *et al.*, U.S. Patent No. 5,795,909 has been maintained.

The present invention is directed to a rapidly disintegrable solid preparation comprising granules or fine granules of lansoprazole, a sugar and a low-substituted hydroxypropylcellulose having 5% to less than 7% of hydroxypropoxyl groups; a method for preparing a rapidly disintegrable solid preparation as well as a method for improving fast disintegrability of a solid preparation. Applicants do not believe that their invention, as set forth in the present claims, is taught or suggested by the combination of the cited references, as they do not believe there is any motivation to combine these two references.

Ohno *et al.* is directed to solid pharmaceutical preparations. Lansoprazole, the active ingredient set forth in independent claim 1, is neither taught nor suggested by the cited reference. Moreover, the cited reference also does not teach or suggest the low-substituted hydroxypropylcellulose having 5% to less than 7% by weight of hydroxypropoxyl groups.

The deficiencies of Ohno *et al.* are not cured by Shashoua *et al.* The Examiner has indicated previously (Paper No. 7) that the reference '909 has been added for the teaching of active ingredients. However, there is no incentive to combine a reference directed to formulations designed for fast buccal disintegratibility and dissolubility with a reference directed to conjugates of cis-docosahexaenoic acid and taxanes useful in treating cell proliferative disorders. Noting that (1) no examples of any formulations of the conjugates were prepared (see columns 9 and 10, wherein test ***solutions*** were of conjugates in ethanol); (2) that the specification indicates that ***intravenous*** routes of administration for the conjugates are preferred (col. 49, line 32); (3) no indication of the presently claimed sugar and specific L-HPC components are mentioned by the cited reference (col. 47, line 59 – col. 48, line 17) and (4) that other delivery systems for the conjugate to treat mammalian cell proliferative disorders include time-release, delayed release or sustained release delivery systems, which act completely differently from the presently claimed rapidly disintegrable solid preparations (col. 49, line 62-col. 50, line 20), Applicants do not find any incentive for combining the teachings of this reference with that of Ohno *et al.*, wherein specific types of formulations were designed for fast buccal disintegratibility and dissolubility.

For this reason, Applicants submit that their invention, as set forth in independent claims 1, 18 and 19 is neither taught nor suggested by the combination of the cited references. Claims 2-7 and 13 depend upon claim 1, so Applicants submit that these more specific dependent claims are also non-obvious. Claims 14-17 have been cancelled. Therefore, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. Sec. 103(a) over Ohno *et al.*, U.S. Patent No. 5,958,453 in view of Shashoua *et al.*, U.S. Patent No. 5,795,909.

IV. Discussion of the New Claims

By this amendment, new independent method claims 20 and 21 have been added to indicate the improved rate at which buccal dissolution time occurs when the specified L-HPC is utilized. Support for the amendment may be found on page 27, line 5 *inter alia*. Moreover, six additional dependent claims have been added, in accordance with the teachings of the present specification at page 27, lines 5-6, *inter alia*.

In the comparative examples 3, 4 and 5 of the '453 reference, wherein an L-HPC was included in the formulation, buccal dissolution time was considerably longer than the 0.1 – 1.0 minute range cited in col. 6, lines 66 and 67. Applicants have previously demonstrated that the

L-HPC component now claimed was unavailable at the time of the '453 work. For this reason, the results which Applicants have now achieved in the present invention were unattainable by the methods of the '453 reference. The L-HPC of the '453 reference as a component in a solid pharmaceutical preparation did not and could not produce the results in the range of dissolution times now claimed. Therefore, Applicants submit that there is no teaching or suggestion of the invention as set forth in independent method claims 20 and 21, nor of new dependent claims 22-29.

V. Conclusion

Consideration and allowance of the claims 1-7, 13 and 18-29 in view of the arguments made above is solicited. Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, she is respectfully requested to call Applicants' attorney.

Respectfully submitted,

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